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JUL 0 6 2000

Attachment 1

510(k) Summary of Safety and Effectiveness

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1.0 Submitter Information

1.1 Submitter: Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, Ohio 44080-2371
ph: (330) 425-1313
fax: (330) 425-1410

1.2 Contact: Douglas J. Thistlethwaite

1.3 Date: April 24, 2000

2.0 Device Name

2.1 Classification Name: System, Nuclear Magnetic Resonance Imaging

2.2 Classification Number: 90LNH

2.3 Trade/Proprietary Name: AIRIS® II Version 4.1 Software

2.4 Predicate Device(s): AIRIS II Magnetic Resonance Imaging System with Version 3.0 Software

Philips Gyroscan NT with Extended Diffusion Package MRI System

General Electric Signa Profile/*i* MRI System

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3.0 Device Intended Use

The MR system is an imaging device and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The MNR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

The indications for use are as follows:

Anatomical Region:	Head, Body, Spine, Extremities
Nucleus excited:	Proton
Diagnostic uses:	T1, T2, proton density weighted imaging
	Diffusion weighted imaging
	MR Angiography
	Image processing
Imaging capabilities:	2D, 3D Spin Echo (SE) * *with re-phasing
	2D, 3D Fast Spin Echo (FSE) *, Fast Inversion Recovery (FIR) *
	2D Inversion Recovery (IR) *
	2D, 3D Gradient Field Echo (GE) *
	2D, 3D Steady State Acquisition with Rewinded GE (SARGE™)*
	2D, 3D RF-spoiled SARGE (RSSG) *
	2D, 3D Time-reversed SARGE (TRSG) *
	2D Spin Echo-Echo Planar Imaging (SE-EPI)
	MR Angiography*
	Half echo, high resolution/high definition, sloped slab profile, magnetization transfer contrast, 2D/3D TOF, 2D/3D TOF RSSG
	ECG, Peripheral, and Respiratory Gating
	RF Coil Uniformity
	Adaptive Image post-processing
	ACR/NEMA/DICOM 3 compliant
	Interventional MR Package
	Aids in the performance of minimally invasive, diagnostic, therapeutic, interventional and intra-operative surgical procedures of the head, body, and extremities that may be facilitated by real-time MR guidance. Such procedures must be performed with MRI-compatible instrumentation, as selected and evaluated by the clinical user.

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4.0 Device Description

4.1 Function

The AIRIS II V4.1 Operating System Software is a modification of the AIRIS II Magnetic Resonance Imaging Systems utilizing V3.0 Operating System Software. The software has been revised to V4.1 to increase the clinical utility of the AIRIS II Magnetic Resonance Imaging System.

Version 4.1 Operating System revisions include new image acquisition sequences and features as follows:

- Respiratory gating
- Spin Echo-Echo Planar Imaging (SE-EPI)
- Diffusion Weighted Echo Planar Imaging (DWI-EPI)

Version 4.1 Operating System revisions include improved image acquisition sequences and features as follows:

- Adaptive Image reconstruction enhancements based on matrix size or MR Angiography sequence
- 3D Maximum Intensity Projection (MIP) interpolation enhancement
- Added Multi-gate Delay to cardiac and peripheral pulse gating
- Added cardiac and peripheral pulse gating for the Steady State Free Precession (SSFP) sequence
- Increased slab overlap in Multiple Overlap Thin Slice Acquisition (MOTSA)
- Added a Shot Number parameter to FSE/FIR protocols
- Increased the slice count in dynamic scanning
- Added filters to available acquisition data filters
- Increased maximum TR on FSE/FIR sequences
- Added fluoro on Time Reversed SARGE™ sequences

Version 4.1 Operating System Software also includes various user interface and processing improvements to increase the clinical utility of the system.

4.2 Scientific Concepts

Magnetic Resonance Imaging (MRI) is based on the fact that certain atomic nuclei have electromagnetic properties that cause them to act as small spinning bar magnets. The most ubiquitous of these nuclei is hydrogen, which makes it the primary nuclei currently used in magnetic resonance imaging. When placed in a static magnetic field, these nuclei assume a net orientation or alignment with the magnetic field, referred to as a net magnetization vector. The introduction of a short burst of radiofrequency (RF) excitation of a wavelength specific to the magnetic field strength and to the atomic nuclei under consideration can cause a re-orientation of the net magnetization vector. When the RF excitation is removed, the protons relax and return to their original vector. The rate of relaxation is exponential and

varies with the character of the proton and its adjacent molecular environment. This re-orientation process is characterized by two exponential relaxation times, called T1 and T2.

A RF emission or echo that can be measured accompanies these relaxation events. The emissions are used to develop a representation of the relaxation events in a three dimensional matrix. Spatial localization is encoded into the echoes by varying the RF excitation, applying appropriate magnetic field gradients in the x, y, and z directions, and changing the direction and strength of these gradients. Images depicting the spatial distribution of the NMR characteristics can be reconstructed by using image processing techniques similar to those used in computed tomography.

4.3 Physical and Performance Characteristics

MRI is currently of great interest because it is capable of producing high quality anatomical images without the associated risks of ionizing radiation. The biological properties that contribute to MR image contrast are different from those responsible for x-ray image contrast. In MR imaging, difference in proton density, blood flow, and T1 and T2 relaxation times can all contribute to image contrast. By varying the pulse sequence characteristics, the resulting images can emphasize T1, T2, proton density, or the molecular diffusion of water or other proton containing molecules.

5.0 Device Technological Characteristics

The technological characteristics of this device are identical to the primary predicate device. There has been no change to the basic hardware design (magnet strength, RF sub-system, gradient sub-system, or control system). The base elements of the operating system software are identical to the primary predicate device.

6.0 Conclusions

It is the opinion of Hitachi Medical Systems America that the AIRIS II V4.1 Operating System Software is substantially equivalent to the AIRIS II Magnetic Resonance Imaging Systems utilizing V3.0 Operating System Software, the Philips Gyroscan NT with Extended Diffusion Package, and the GE Signa Profile/*i*. The technological characteristics and intended use are identical to the Predicate Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 06 2000

Doug Thistlethwaite
Manager, Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, Ohio 44087

Re: K001334
AIRIS II Version 4.1 Operating System Software
Dated: April 24, 2000
Received: April 27, 2000
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Thistlethwaite:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K001334

Device Name: AIRIS II V4.1 Operating System Software

Indications for Use:

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Anatomical Region: Head, Body, Spine, Extremities

Nucleus excited: Proton

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- Image processing

Imaging capabilities:
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- MR Angiography *
  - Half echo, high resolution/high definition, sloped slab profile, magnetization transfer contrast, 2D/3D TOF, 2D/3D TOF RSSG
- ECG, Peripheral, and Respiratory Gating
- MR Fluoroscopy
- RF Coil Uniformity
- Adaptive Image post-processing
- ACR/NEMA/DICOM 3 compliant
- Interventional MR Package
  - Aids in the performance of minimally invasive, diagnostic, therapeutic, interventional and intra-operative surgical procedures of the head, body, and extremities that may be facilitated by real-time MR guidance. Such procedures must be performed with MRI-compatible instrumentation, as selected and evaluated by the clinical user.

*with re-phasing

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001334

Prescription Use ✓ OR Over-the-Counter Use _____